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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/523,912	03/09/2000	Raymond W. Cohen	3896-006	5945

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EXAMINER	
BOCKELMAN, MARK	

ART UNIT	PAPER NUMBER
3762	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/523,912	Applicant(s) COHEN ET AL.	
	Examiner Mark W Bockelman	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 February 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The term "output member' is not associated with any structure in the specification and thus it is difficult to determine what the term is supposed to encompass. In claim 1, it appears that the "output member" is a printer or other display device that is part of the external monitor system. In claims 9 and 18 it appears the "output member" is the data transmission cable between the external monitor and defibrillator. The examiner requests applicant to clarify the specification as to what structure(s) constitute the "output member" that is being claimed.

Claim Rejections - 35 USC § 112

Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 17 is confusing and appears to be an error in that it is narrative in nature and thus not written in proper claim language and it lacks proper antecedent and/or dependency.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6-9, 12-13, 16-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Hakala et al. USPN 4,635,639.

Hakala et al. teach a patient monitor 10 having a sensor 132, 144, 130 and a signal processor 134 and output member(s) 158, 136 (CRT), 162 and recorder (printer 114, 16). A defibrillator unit 12, which includes a pacing unit 48 can be coupled to the monitor either via optical coupling (60,62,64) or electrical coupling (82). The defibrillator has a pulse generator 182 which is responsive to commands either by operator manual input to operate it separately (column 4 lines 23-37), or by r wave sening performed by the ecg monitor to synchronize pulsing. Upon entry of various defibrillation settings, the settings are received by data generator (102) and transferred to the ecg monitor as "indication signals" that are output by output member 162 to recorder 114, 16 . See column 6 lines 40-45. The CRT provide a display and the recorder a hard copy printout. The ecg monitor may operate using monitor ecg sensors 144 or defibrillation pad sensors 30-32. The defibrillator monitor includes a selector arranged in the form of a display (reference numerals 32, 34, 36) that displays the settings input by observing the dial and push button status. The devices may be used in independent or in integrated operation (column 1 lines 8-10)

In regards to claim 9, cable 82 forms a mechanical and electrical connection between the devices in a similar fashion as applicant's cables 40 and 38 in figure 1 for performing the function. The examiner considers the

physiological sensor to be either the monitor ecg leads or the defibrillator paddles and sensing circuit. The controller 112 detects r –waves and issues commands to generate synchronization signals to pulse generator 182. Output member 100 sends signals concerning the defibrillator operation to the external monitor for display which may include annotations regarding defibrillation firing (i.e. pulse generation – see column 6 lines 40-45). In regard to claim 12, the examiner consider the synchronize pulsing to be automatic for defibrillation as well as pacing , the manual and advisory modes can be performed by the person observing the ecg.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4-6, 10-11, 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hakala et al. USPN 4,635,639 in view of Reyes USPN 4,974,600 and Lin et al. USPN 6,246,907.

Applicant differs from Hakala et al in reciting that the monitor transmits ecg signals to the defibrillator, the monitor measures blood pressure, the defibrillator has an arrythmia detector as well as an alarm for alerting operational conditions.

Reyes teaches a similar system having an external monitor and a defibrillator that can be quickly attached to a monitor that is in use with a patient such as in the Hakala et al device. Reyes shows that that it was known to include a display on the defibrillator itself for its ability to operate independently as well as receive ecg signals from the external monitor wherein the defibrillator determines the need for treatment. Reyes also teaches that it was known to include several physiological measuring devices together including ecg and blood pressure displaying devices (column 1 lines 25-30). Lin et al. also teaches a display on a defibrillation device and that an arrythmia detector maybe incorporated into a defibrillator unit. An interface (86) maybe be used for exchanging information with external devices. To have provided the Hakala defibrillator with a display that receives ECG information from and external monitor and to use it for controlling automated or manual shock therapy via and arrythmia detector would have been obvious in view of the collected teachings of Reyes and Lin et al. Lin et al also teaches the use of alarms to indicate the operation of the system to indicate potential shock situations to the user. (see column 7 lines 35-45).

Claims 1-14, 16-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin et al. USPN 6,246,907 in view of Hakala et al. USPN 4,635,639 and Reyes USPN 4,974,600

Lin et al. teach a defibrillator that can receive ECG signals from sensor pads 60, which has an arrythmia detection unit and may be used in various automated or manual modes. Information may be exchanged with other devices including sending ECG to other monitors (column 4 Lines 40-45). The device may generate alarms to indicate conditions of the device. (column 7 lines 35-45). Applicant differs in claim 1 in reciting that the external monitor has a sensor system and differs in claims 9 and 18 in that the defibrillator sends messages to the ECG monitor to indicate the status of operation. Reyes and Hakala both teach the connection of defibrillators to external monitors tha include their own set of ECG. In addition, Hakala teaches that various defibrillator operating information concerning the operation of the defibrillator such as annotations as to when pulses are delivered to the patient maybe sent from the defrillator to the external monitor for displaying (printouts). To have connected the Lin et al device to an external monitor that has its own ECG leads would have been obvious for saving time during emergency situations as described by Reyes and Hakala. Furthermore, to have sent various setting information as well as pulse delivery information to the external monitor along with the ECG information for providing a display of such would have been obvious in view of Hakala. Including other physiological sensors in the external monitor would have been obvious in view of the background discussions in Reyes and Lin et al.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hakala et al. USPN 4,635,639 and Reyes USPN 4,974,600 as applied to claims 1-14, 16-22 above, and further in view of Morgan et al USPN 5,782,878. To have included network link to provide information to a central communication station regarding the operation and use of the defibrillator of Lin et al would have been obvious in view of Morgan et al.

Response to Arguments

Applicant's arguments with respect to claims 1-22 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory

action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark W Bockelman whose telephone number is (703)-308-2112. The examiner can normally be reached on Monday - Thursday 10-8:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MARK BOCKELMAN
PRIMARY EXAMINER

April 17, 2004

MWB